REMARKS

The claims have been amended to specify that the claimed composition is free of organic solvents as taught in the specification in the penultimate paragraph on page 2.

A new inventor declaration is in the process of being executed and will be forwarded to the PTO in due course.

The rejection of claims 1-30 under 35 U.S.C. § 112, second paragraph, as being indefinite with the reference to what constitutes "co-crystals of florfenicol". This term is well known in the pharmaceutical field as relating to crystals comprising a pharmaceutically active compound and other non-active compounds, which may include solvents, in the crystals. See the article submitted with the IDS filed on January 14, 2010. Since the term is well understood and definite to those of ordinary skill in the art, it is respectfully submitted that this rejection should be withdrawn.

The rejection of claims 11-30 under 35 U.S.C. § 103 over Nagabhushan in view Kruse is respectfully traversed.

The present invention relates to a pharmaceutical composition which is an aqueous injectable suspension containing micronized florfenicol at a concentration of up to 500 mg/ml in which the composition does not contain organic solvent beyond that which may be in the co-crystals. As pointed out in the opening paragraphs of this application, injectable formulations of this drug were known in the art but contained organic solvents or mixtures of water and organic solvent. Florfenicol has a low solubility in water which is enhanced by the presence of the organic solvents. It has been found that the organic solvent makes the florfenicol susceptible to hydrolyzation because of the increased dissolution but that aqueous solutions free of organic solvents do not hydrolyze florfenicol micronized co-crystals.

The Nagabhushan reference is merely confirmatory of the prior art described in the application. It describes various florfenicol formulations but they contain organic solvents.

Formulation 1 noted by the Examiner is an oral suspension which contains 5% by weight of propylene glycol and formulation 5, the only other suspension or injectable, contains 500 mg/ml of N,N-dimethylacetamide. There is nothing in this reference which teaches or suggests that the formulation should be free of organic solvents.

The Kruse reference has been cited to teach various aspects of the claims but not to teach or suggest an injectable suspension which lacks organic solvent.

Because of the basic deficiencies in the combination of references discussed above, it is not necessary to address any of the other contentions made in the outstanding Office Action. Nevertheless, the lack of response should not be taken as acquiescence but is merely an indication that the assertions made are moot.

In light of the foregoing considerations, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a notice of allowance is respectfully solicited.

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Respectfully submitted,
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